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CENTRAL FAX CENTER

MAY 01 2008

Application No. 09/626,636  
Amendment dated May 1, 2008  
Reply to Office Action of February 1, 2008

**REMARKS**

Applicant cancelled claims 209, 213, and 214 without prejudice or disclaimer of their subject matter, and amended claims 172, 207, 210-212, 248, 289, 320, 342, and 350 to further define Applicant's invention.

In the Office Action, the Examiner objected to dependent claims 320-322 for depending from a cancelled claim. In response, dependent claim 320 has been amended to depend from Independent claim 289. Accordingly, Applicant submits that the Examiner's objection has been overcome.

The Examiner rejected claims 172-176, 178-184, 201, 202, 247, 331, and 344-346 (including independent claim 172) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,878,915 to Brantigan ("Brantigan"), U.S. Patent No. 5,192,293 to Cartwright ("Cartwright"), and U.S. Patent No. 5,049,150 to Cozad ("Cozad"). Furthermore, the Examiner also rejected claims 248-256, 258-269, 276, 278-286, and 347-349 (including independent claim 248) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Cartwright, and Cozad. As discussed below, Applicant submits that independent claims 172 and 248, as amended, overcome the Examiner's rejections thereof under 35 U.S.C. § 103(a) based on Brantigan, Cartwright, and Cozad.

In KSR International Co. v. Teleflex Inc. et al., the Supreme Court reaffirmed the framework for governing obviousness under 35 U.S.C. § 103(a) as set forth in Graham et al. v. John Deere Co. of Kansas City et al., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). (See KSR v. Teleflex, 127 S.Ct. 1727 (2007)). Under Graham v. John Deere, the question of obviousness is resolved on the basis of factual determinations including (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) where in evidence, so-called secondary considerations. (See Graham v. John Deere, at 17-18, 148 U.S.P.Q. at 467.) However, even under Graham v. John Deere, prior art that is non-analogous to the claimed invention, references that teach from a combination thereof, or a combination of references that does not teach or suggest

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every element of the claimed invention support a finding of nonobviousness. Applicant submits that Cartwright is non-analogous art, that Brantigan and Cozad teach away from Cartwright, and that, even if the combination of Brantigan, Cartwright, and Cozad was viable, the combination thereof does not teach or suggest Applicant's invention as claimed in amended independent claims 172 and 248.

Note that Cartwright discloses a drill guide (24) for passing a drill bit (formed from a drill burr (48) and a tool shank (50)) therethrough into an orbital implant (10). The drill guide (24) includes a cylindrical housing (26) having an interior bore (30) for passing the drill bit therethrough. A fixed end (32) is press-fit into one end of the interior bore (30). The fixed end (32) includes a concave end surface (34) for engaging the implant (10), and a bore (38) for receiving the drill bit therethrough. According to Cartwright, the concave end surface (34) is "shaped to generally conform to the radius of curvature of Implant (10)." (See Cartwright, col. 2, lines 53-56.) Accordingly, Cartwright teaches that, when engaging an implant, the surface contacting the implant must conform to the shape thereof.

According to MPEP § 2141.01, "a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." Hence, the pertinence of a reference is determined by if the reference can be logically associated with the claimed invention.

Applicant submits that the drill guide (24) of Cartwright for contacting the orbital implant (10) is not logically associated with the claimed invention. The drill guide (24) is an instrument used in eye surgery, not an orthopedic instrument. Furthermore, the drill guide (24) is not for contacting bone (instead it only contacts the implant (10)), and is not used for passing the implant (10) therethrough (instead it only passes the drill bit therethrough). As such, Cartwright is non-analogous art to the claimed invention. Accordingly, Applicant submits that Cartwright cannot be used as the basis for an obviousness rejection of independent claims 172 and 248.

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Furthermore, Applicant submits that Brantigan and Cozad teach away from Cartwright. Brantigan discloses a drill guard (22) including teeth or prongs (23). The teeth (23) of Brantigan appear to terminate at a plane perpendicular to the longitudinal axis of the drill guard (22). Furthermore, Cozad discloses a second member (14) including a plurality of teeth (36) for passing a drill-tipped first member (12) therethrough. Like the teeth (23) of Brantigan, the plurality of teeth (36) also appear to terminate at a plane perpendicular to the longitudinal axis of the second member (14). Both the teeth (23) of Brantigan and plurality of teeth (36) of Cozad engage bone. Neither of the ends of Brantigan and Cozad including the teeth (23) and the plurality of teeth (36), respectively, are contoured to conform to the shape of the bone being engaged. Cartwright teaches use of the contoured end surface (34), but, when contacting bone, Brantigan and Cozad teach having the teeth and the plurality of teeth (36), respectively, terminate at a plane perpendicular to the longitudinal axes of their respective instruments. As such, besides being non-analogous art, Applicant submits that Brantigan and Cozad teach away from Cartwright.

Applicant also submits that, unlike amended independent claims 172 and 248, Brantigan, Cozad, and Cartwright do not teach or suggest an apparatus for use in performing human interbody surgery including a hollow tubular guard (claim 172) or a hollow guard (claim 248) with a distal end having "a concave curvature being at least in part curved in a single plane parallel to the mid-longitudinal axis," where the concave curvature of the distal end has "a middle portion and opposed portions on either side of said middle portion, said middle portion being closer to said proximal end than said opposed portions."

As discussed above, the ends of Brantigan and Cozad including the teeth (23) and the plurality of teeth (36), respectively, terminate at a plane perpendicular to the longitudinal axes of their respective instruments. As such, unlike independent claims 172 and 248, Applicant submits that neither Brantigan nor Cozad have a distal end with a concave curvature being at least in part curved in a single plane parallel to the mid-longitudinal axis of the drill guard (22) and the second member (14), respectively.

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Furthermore, the concave end surface (34) of Cartwright is shaped to conform to the radius of curvature of the implant (10). Therefore, because the implant (10), by its very nature, is spherical, the concave end surface (34) would also be spherical. As such, unlike Independent claims 172 and 248, Applicant submits that Cartwright does not have a distal end having a concave curvature being at least in part curved in a single plane parallel to the mid-longitudinal axis, where the concave curvature of the distal end has a middle portion closer to the proximal end than opposed portions on either side of the middle portions. Accordingly, the obviousness rejection of independent claims 172 and 248 based on a combination of Brantigan, Cozad, and Cartwright cannot be maintained.

Additionally, the Examiner rejected claim 350 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Cartwright, Cozad, and Codman (Ruptured Cervical Intervertebral Discs article). As discussed above, Cartwright is non-analogous art to the claimed invention. Furthermore, because a drill guide of Codman is directed to contacting bone, Cartwright teaches away from Codman in similar fashion to Brantigan and Cozad. Also, as discussed in the Amendment of October 31, 2007, Codman discloses a drill guide used in spinal surgery. The contact surface of the drill guide, as shown in Fig. 21 of Codman, appears to be flattened. Therefore, unlike amended independent claim 350, neither Brantigan, Cartwright, Cozad, nor Codman teach or suggest an apparatus for use in performing human interbody surgery including a tubular guard with a distal end having "a concave curvature being at least in part curved in a single plane parallel to the mid-longitudinal axis," where the distal end forms "at least in part a cylindrical surface transverse to the mid-longitudinal axis." Accordingly, Applicant submits that the obviousness rejection of independent claim 350 based on Brantigan, Cartwright, Cozad, and Codman cannot be maintained.

The Examiner rejected claims 207-218, 220-226, 237, and 238 (including independent claim 207) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Cozad, and Codman. Independent claim 207, as amended, includes the recitations of dependent claims 209, 213, and 214. Amended independent claim 207

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recites an apparatus for use in performing human interbody spinal surgery including a hollow tubular guard having "at least two slots in said sides, said slots divide at least a portion of said guard into an upper portion and a lower portion, said upper portion and said lower portion being adapted to move apart from one another to facilitate insertion of an Implant." Neither Brantigan, Cozad, nor Codman teach or suggest a hollow tubular guard including at least two slots dividing the hollow tubular guard into an upper portion and a lower portion adapted to move apart from one another to facilitate insertion of an implant. Accordingly, Applicant submits that the obviousness rejection of independent claim 207 based on Brantigan, Cozad, and Codman cannot be maintained.

The Examiner rejected claims 289-304, 306-318, and 323-329 (including Independent claim 289) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan, Cozad, and Codman. As discussed above, Brantigan discloses the drill guard (22), Cozad discloses the second member (14), and Codman discloses the drill guide, each of which are provided for passing a drill therethrough. Brantigan, Cozad, and Codman do not teach or suggest passing an Implant through the drill guard (22), the second member (14), and the drill guide, respectfully. Accordingly, neither Brantigan, Cozad, nor Codman teach or suggest an apparatus for use in human lumbar interbody spinal surgery including "a hollow guard having a passage for providing guided access to a disc space and vertebral bodies adjacent the disc space to pass an implant therethrough," "an implant sized for passage through said passage of said guard," and "an implant driver sized in part for passage through said passage of said guard for passing said implant through said guard and into an Implantation space," as recited in Independent claim 289. Accordingly, Applicant submits that the obviousness rejection of Independent claim 289 based on Brantigan, Cozad, and Codman cannot be maintained.

The Examiner rejected claims 332, 335-337, 339, and 341-343 (including independent claim 332) under 35 U.S.C. § 103(a) as being unpatentable over Brantigan and Cozad. However, neither Brantigan nor Cozad include an apparatus for use in

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human lumbar interbody spinal surgery including a hollow guard having "a wall that is continuous around the mid-longitudinal axis of said guard," and "an opening through said wall," as recited in independent claim 332. Accordingly, Applicant submits that the obviousness rejection of Independent claim 332 based on Brantigan and Cozad cannot be maintained.

Additionally, the Examiner rejected dependent claims 190-195 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cartwright and Cozad as applied to claim 172 above, and further in view of Codman; rejected dependent claim 219 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad and Codman as applied to claim 207 above, and further in view of Cartwright; rejected dependent claims 270-275 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cartwright and Cozad as applied to claim 248 above, and further in view of Codman; rejected dependent claims 287 and 288 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cartwright and Cozad as applied to claim 286 above, and further in view of U.S. Patent No. 5,357,983 to Mathews ("Mathews"); rejected dependent claim 305 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad and Codman as applied to claim 289 above, and further in view of Cartwright; rejected dependent claims 329 and 330 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad and Codman as applied to claim 328 above, and further in view of Mathews; rejected dependent claims 333 and 334 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad as applied to claim 332 above, and further in view of Mathews; rejected dependent claim 338 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad as applied to claim 332 above, and further in view of Cartwright; and rejected dependent claim 340 under 35 U.S.C. § 103(a) as being unpatentable over Brantigan in view of Cozad as applied to claim 332 above, and further in view of Codman. Applicant submits that the rejections of claims 190-195, 219, 270-275, 287, 288, 305, 329, 330, 333, 334, 338, and 340 are rendered moot at least because these claims depend from an allowable independent claim, or claims dependent therefrom.

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In conclusion, Applicant submits that independent claims 172, 207, 248, 289, 332, and 350 are patentable and that dependent 173-176, 178-184, 190-195, 201, 202, 208, 210-212, 215-226, 237, 238, 247, 249-256, 258-276, 278-288, 290-318, 320-331, and 333-349 dependent from independent claims 172, 207, 248, 289, or 332, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim. Therefore, in view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Accordingly, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN &amp; FERRARO, LLP

Dated: May 1, 2008By: 

Thomas H. Martin

Registration No. 34,383

1557 Lake O'Pines Street, NE  
Hartville, Ohio 44632  
Telephone: (330) 877-0700  
Facsimile: (330) 877-2030